Tentative translation

Food Safety Risk Assessment Related to the Proposed Partial Revision of the Specifications of Composition to Abolish the Application of the *E. coli*-Negative Requirement to Frozen Bread Dough and Its Variations, the Main Ingredient of Which is Wheat Flour and Which Require Heating Treatment before Consumption

Report

April 2006
Food Safety Commission

<History of the risk assessment>

August 23, 2005	The Food Safety Commission was asked by the Minister of Health, Labor and Welfare—the commission received related documents—to conduct food safety risk assessment related to the proposed partial revision of the specifications of composition to abolish the application of the *E. coli*-negative requirement to frozen bread dough and its variations, the main ingredient of which is wheat flour and which require heating treatment before consumption.
August 25, 2005	The 108th Meeting of the Food Safety Commission (requirements explained)
September 6, 2005	The 7th Meeting of the Microorganisms Expert Committee
November 15, 2005	The 10th Meeting of the Microorganisms Expert Committee
December 27, 2005	The 11th Meeting of the Microorganisms Expert Committee
February 15, 2006	The 13th Meeting of the Microorganisms Expert Committee
March 9, 2006	The 134th Meeting of the Food Safety Commission (report)
March 9 to April 5, 2006	Hearing of the public opinion
April 27, 2006	The 141st Meeting of the Food Safety Commission (reporting) (Notified to the Minister of Health, Labor and Welfare as of the same day)

In alphabetical order

<Members of the Food Safety Commission>

Chairman	Masaaki Terada
	Motoko Sakamoto
	Naoko Koizumi
	Seiichi Honma
	Tadao Terao
	Takeshi Mikami
	Yasuhiko Nakamura

<Expert Committee Members of the Microorganisms Expert Committee, Food Safety Commission>

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	Fumiko Kasuga
	Hiroshi Fujikawa
	Masayuki Nakamura
	Nobuhiko Okabe
	Nobuyuki Terakado
	Shunji Kozaki
	Soichi Makino
	Tateo Fujii
	Tsutomu Maruyama
	Tsutomu Sekizaki
	Yoshichika Arakawa
	Yukiko Kudo

<Adviser>

Shizunobu Igimi
Chief of 1st Laboratory, Division of Biomedical Food Research, National Institute of Health Sciences
(The 10th Meeting of the Microorganisms Expert Committee, November 15, 2005)
(The 11th Meeting of the Microorganisms Expert Committee, December 27, 2005)

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1 Introduction

The Food Safety Commission (FSC) was asked by the Ministry of Health, Labor and Welfare (MHLW), in accordance with the stipulation in Article 24, paragraph 1 of the Food Safety Basic Law (Law No. 48 in 2003), to set forth its views—in relation to the specifications and standards for frozen foods—on food safety risk assessment related to the proposed partial revision of the specifications of composition to abolish the application of the *E. coli*[i]-negative requirement to frozen bread dough and its variations, the main ingredient of which is wheat flour and which require heating treatment before consumption (Food Safety Notice No.0823004; dated August 23, 2005; issued by the MHLW)[1].

2 Consultation on the Food Safety Risk Assessment

2.1 Background

Frozen bread dough and its variations (including pizza dough, pie dough, etc.; the same shall apply hereafter), the main ingredient of which is wheat flour, are categorized based on the Japanese Food Sanitation Law as "frozen food suitable for consumption after heating" (not heat-treated before being frozen) in the specifications and standards for food and food additives. The law requires all the foods categorized in this group to test negative for *E. coli*[2]. However, there is an indication that it is too difficult to apply the current specifications of composition to imported frozen bread dough and its variations due to the nature of the foods; therefore, a request for reappraisal of the specifications and standards was made to the MHLW. Based on the judgment that a reappraisal of the specifications and standards needs to be considered, given that the issue involves global trading, the MHLW asked the FSC to conduct food safety risk assessment based on the Food Safety Basic Law[3].

2.2 Description of Consultation

This consultation was a request from the MHLW to the FSC to conduct food safety risk assessment for discerning whether the abolishment of the *E. coli*-negative requirement specifications of composition used in frozen bread dough and its variations, the main ingredient of which is wheat flour and which require heating before consumption, is likely to lead to an increase in health risks. In addition, the MHLW, while indicating its intention to consider reappraisal of the specifications of composition of not only frozen bread dough and its variations but also of other frozen foods in

[i] Definition of *E. coli* is specified in the test method based on the Food Sanity Law. *E. coli* are bacteria that generate gas when incubated in an EC fermentation vial at 44.5 ± 0.2°C for 24 ± 2 h; moreover, they are confirmed as coliform group or fecal coliform group based on a test similar to the coliform group test. On the other hand, the Food Sanitation Inspection Guideline considers *E. coli* as the coliform bacteria that show the pattern [++--] when the indole, methyl red, Voges-Proskauer, and citrate (IMViC) tests are conducted according to the specified procedure. In order to discriminate the two concepts, *E. coli* is expressed as "*E. coli*" in this report. Accordingly, "*E. coli*" refers to bacteria that are slightly different from *Escherichia coli* based on the taxonomic category or bacteria called coliform bacteria in other countries.

the future depending on the result of the current food safety risk assessment, explained that conducting food safety risk assessment on the frozen bread dough and its variations, for which a relatively large amount of data had already been obtained compared to other frozen foods, is necessary as the first step[4].

The MHLW had already investigated information concerning the actual contamination status in frozen bread dough, including the raw materials, at home and abroad from local documents as well as from those derived from foreign government agencies; they also investigated, among other things, the specifications and standards on frozen foods existing in foreign countries, baking conditions for frozen bread dough, and the death dynamics of *E. coli* and other bacteria following heat treatment. These were done prior to the consultation provided to the FSC regarding the frozen bread dough and its variations. This time, the results of the above investigations were submitted to the FSC as data[5,6,7,8].

3 Food Safety Risk Assessment

3.1 Hazard Identification

With respect to the current consultation, the characteristics of *E. coli* as an indicator bacterium and the scope and characteristics of frozen bread dough and its variations are described as follows.

3.1.1 Characteristics of *E. coli* as an Indicator Bacterium for Fecal Contamination

E. coli is used as an indicator for fecal contamination in the specifications of composition in frozen foods to be consumed after heating (the food is unheated immediately before freezing) and, as such, is not considered to be obviously pathogenic by itself. The existence of these bacteria does not indicate the possibility that they may exert a direct influence on health; however, it implies that intestinal pathogenic bacteria may be present and that *E. coli* is considered as an indicator for these bacteria. In addition, it has been reported that the D value[ii] for *E. coli* is 0.26 to 2.64 at 60°C and 0.16 at 64.3°C[3].

3.1.2 Frozen Bread Dough and Its Variations

According to the explanation provided by the MHLW, the subjects for the current assessment, the frozen bread dough and its variations, are summarized as below:

(1) Definition of frozen bread dough and its variations

"Frozen bread dough and its variations" are defined as frozen bread dough and its variations (including pizza as well as bread dough) made with wheat flour as the main ingredient that require heat treatment before consumption and are generally regarded as unedible without being subjected to heating at a central temperature of 85°C for 1.5 min or more[1,2,3,5].

Commercially sold frozen breads in Japan are basically classified into

[ii]Value of the heating time required to decrease the originally existing bacterial counts to 1/10; it is expressed in minutes.

six types: plain breads, hard rolls, sweetened buns, donuts, Danishes, and pies. Danishes and pies contain layers of fat between the folded dough. Except pies, all other breads contain yeast. In addition, some breads are frozen after being filled with sweetened red-bean paste, cream, curry, and so on[3].

On the other hand, brown n' serve[iii], a food that is heated before being frozen, is not categorized as frozen bread dough or its variation.

(2) Manufacturing method

In the manufacturing process for frozen bread dough, the shaping of breads from raw materials is finished in a temperature-controlled factory with the temperature set in advance at approximately 20°C to 24°C or lower; this process takes approximately two and a half hours. With the cooling process included, the shaping of breads is complete within seven hours, following which the breads are flash-frozen[3,9].

(3) Import Statistics

With respect to the import statistics of frozen bread dough and its variations, 4,064 cases of import notifications were submitted for 15,400 tons of the relevant foods in 2003. Of the above, 277 cases were inspected; out of which four cases were found to be noncompliant with the requirements for import permit due to the presence of an *E. coli*-positive test result.

On the other hand, the domestic bread production was 1,242,951 tons (consumption of wheat flour for bread production including plain breads and sweetened buns) in 2004, approximately 6% of which were produced with frozen dough (frozen dough consumption was 76,879 tons)[3].

(4) Specifications of Composition under the Food Sanitation Law

Under the Food Sanitation Law, the specifications of composition used in frozen food suitable for consumption after heating (unheated immediately before freezing) is applied to frozen bread dough and its variations. The specifications of these compositions requires a bacteria count of less than 3,000,000 per 1 g of sample and a negative result for *E. coli*, the indicator bacteria for fecal contamination (established in 1973). However, the specifications of composition of bacteria count in general are not applied to fermented foods using yeasts, such as frozen bread dough[2].

(5) Specifications of Composition used in Frozen Foods in Foreign Countries

According to the survey conducted by the MHLW, specifications and standards for frozen foods are established in the United States, China, and Korea[3,8].

- United States

  The United States has specifications of composition used for dough and cookies (cooled or frozen without being baked); these specifications specifies that the count for the coliform group should be <100 most probable number (MPN), that of *Escherichia coli* should be

[iii] A half-baked bread. It is half-braked so that consumers can store the bread longer and can easily enjoy the taste of the bread hot from the oven.

<10 MPN, that of *Salmonella* should be not detectable (ND), that of Staphylococcal enterotoxin should be <10 MPN, and the total bacteria count should be <50,000 cfu/g. However, these specifications were established not for regulatory purposes but as Commercial Item Descriptions (CIDs) for quality assurance by the U.S. Department of Agriculture (USDA).

- China

  China has specifications of composition in flash-frozen instant foods (unheated before flash freezing). The specifications specify that the count of the coliform group should be <240 cfu/g, that of *Escherichia coli* should be ND, that of *Salmonella* should be ND in 25 g, that of Staphylococcal enterotoxin should be ND in 0.01 g, and the total bacteria count should be <300,000 cfu/g.

- Korea

  Similar to Japan, Korea has specifications of composition in frozen foods (unheated before freezing). The specifications specify that the count of *Escherichia coli* should be ND and the total bacteria count should be <3,000,000 cfu/g.

- Other countries

  ・With respect to the specifications and standards for fresh dough, Canada has specifications of composition that specify that *Escherichia coli* test results should meet the criteria of m = 10, M = 100, n = 5, and c = 2. Cuba has specifications of composition that specify that the count of fecal coliform group should be <10 cfu/g (n = 1).

  ・With regard to specifications and standards for wheat flour, Spain has specifications of composition that specify that the count of *Escherichia coli* should be <100 cfu/g.

  ・With regard to specifications and standards for baked breads, Switzerland, Ireland, Netherlands, and Spain have specifications of composition regulating the counts of microorganisms including *Escherichia Coli*. In the standard established by Switzerland, however, a note of caution is included; this note excludes unbaked frozen bread dough from the foods targeted for the application of the *Escherichia coli* criteria.

3.1.3 Actual *E. coli* Contamination Status in Frozen Bread Dough and Its Variations at Home and Abroad

According to the survey undertaken by the MHLW, the actual contamination status for frozen bread dough and its variations are as follows:

(1) Actual status of *E. coli* contamination in frozen bread dough and raw materials in Japan

- In an inspection based on the Specifications of Composition for Frozen Foods on 18 samples of frozen bread dough provided by four domestic manufacturers, the coliform group was detected in six and *E. coli* in one sample. In an inspection performed based on the MPN calculation

method, the coliform group was detected in all the 18 samples, while *Escherichia coli* was detected in two samples. The bacteria count ranged from 4.3×10^3 to 7.1×10^8/g[3,5].

- In wheat flour and yeasts used as raw materials for breads, kneaded flour used in the manufacturing process for breads, and walnut, raisin, baking powder, and rye flour paste used as auxiliary materials, while the coliform group was detected in some samples, no *Escherichia coli* was detected in any of the samples[3,5].

- In an inspection of another manufacturer performed with the use of a laboratory procedure that is 10 times more sensitive than the laboratory procedure specified in the Food Sanitation Law, *E. coli* was detected in 4 out of 14 products and in 4 out of 15 wheat flours. Coliform group was positive in 27 out of the 29 samples[3,5].

- Staphylococcus enterotoxin was not detected in either the raw materials or the products inspected[3,5].

- According to the results obtained following self-inspection of flour by four flour millers provided by the Wheat Flour Institute, Flour Millers Association, no *E. coli*, Staphylococcal enterotoxin, or *Salmonella* have been detected in the past[3,5].

(2) Documentation of Information on the Actual Contamination Status of Frozen Bread Dough and Wheat Flour

According to the data obtained so far in Japan and abroad on the actual contamination status of frozen bread dough and raw materials, *E. coli* contamination of wheat flour possesses the tendency to vary among the producer countries. However, contamination rates, contamination levels, and the sources of contamination are unknown.

- Investigation of domestic and foreign literature revealed that six documents reported the detection of the coliform group in six out of eight samples, and three documents reported the detection of *Escherichia coli* in two out of three samples[3,5].

- With regard to wheat and rye, four documents reported that the coliform group was detected in six out of nine samples, and two documents reported that *Escherichia coli* was detected in one out of nine samples[3,5].

- With respect to wheat flour, seven documents reported that the coliform group was detected in 11 out of 19 samples, and five documents reported that *Escherichia coli* was detected in four out of 13 samples[3,5].

- In case of raw noodles that are not heat-treated in the manufacturing processes—similar to bread dough—nine documents reported that the

coliform group was detected in 15 out of 20 samples, and four documents reported that *Escherichia coli* was detected in four out of six samples[3,5].

- In addition, it has been reported in the United States that, in an inspection of 3,350 samples of wheat flour in total, *Escherichia coli* contamination was detected at an average contamination rate of 12.8% (3.4%–89.3%), irrespective of seasons or the species of wheat[10].

3.1.4 Health Hazard

According to the MHLW, no health hazard caused by frozen food served after heating (other than those heated immediately before freezing) have been reported in Japan[3]. In addition, to the extent of the investigation undertaken by the Microorganisms Expert Committee, no health hazards caused by bread dough and its variations (frozen, refrigerated, or room temperature) have been reported either at home or abroad[11]. Incidentally, although the amount of frozen bread dough distributed is reported to be less than 10% of all the bread doughs[3], given that both foods are made from the same raw materials, it is estimated that they would be contaminated to a similar level by *E. coli*.

3.1.5 Characteristics of Consumer Groups

Given that the relevant foods are consumed by a wide variety of consumers, this food safety risk assessment was performed without limiting the consumer groups targeted for the assessment.

3.2 Risk Characterization

Matters discussed on risk characterization are described below:

(1) According to the investigations performed by the MHLW and the Microorganisms Expert Committee, no health hazards caused by frozen bread dough and its variations have been reported in the past either at home or abroad[3,11]. Accordingly, no severe health hazard is likely to occur in the immediate present from the relevant foods.

(2) According to the investigations performed by the MHLW and the Microorganisms Expert Committee, no health hazard caused by the relevant foods has been reported in the past either at home or abroad in case of room-temperature or cool bread dough and their variations, despite the lack of specific specifications of composition[3,11].

(3) Given that frozen bread dough and its variations need to be baked at a high temperature before consumption, had they been contaminated by *E. coli*, the bacteria would be killed following appropriate heating.

(4) With regard to the coexistence of harmful microorganisms other than those observed in the intestine, given that it is difficult to prevent the damage caused by the other microorganisms even after fulfillment of the *E. coli*-negative specifications in the composition, abolishing the

specifications of composition used in frozen bread dough and its variations will not change the severity of the health hazard. On the other hand, with no reports so far of health hazards caused by specific pathogenic microorganisms derived from bread dough and its variations—not only the frozen ones but also the room-temperature and cool ones—there are no grounds for establishing individual specifications that are applicable to composition and are directed against specific pathogens. However, if a health hazard occurs in the future as a result of contamination by a particular pathogen in the frozen bread dough or its variations, consideration should be given separately for establishing specifications of composition with the relevant microorganism as the target.

(5) Given that the current consultation was provided only on "frozen bread dough and its variations, the main ingredient in which is wheat flour and which require heating before consumption," safety risk assessment for the other frozen foods should be performed separately with respective conditions investigated separately and with data collected and examined even if such foods are similar to frozen bread dough and its variations.

(6) Possible alternative regulations

- Regulation on the bacteria count of *E. coli* or the coliform group
- Establishment of specifications of composition against harmful microorganisms (*Escherichia coli* O157, etc.)

  Materials submitted by the MHLW [12] indicate that, while establishing a microbial specification that specifies the threshold level for bacteria counts, the microorganisms to be controlled and the threshold level of the bacteria counts need to be adjusted based on the microbial investigation data obtained from various foods. This necessitates a wide variety of research data including those on the major contaminants, detection frequencies of pathogenic bacteria, and counts of detected bacteria for foods under various conditions. Establishment of the microbial specification is, however, considered to be difficult at present because the relevant data is insufficient. In addition, given that no serious health hazards are likely to occur and that no health hazard caused by frozen bread dough and its variations has been reported so far either at home or abroad, MHLW indicated that there is little need for establishing a new microbial specification at present. The Microorganisms Expert Committee made deliberations in light of the above views and, as a result, arrived at the conclusion that the establishment of new specifications and standards against harmful microorganisms, including new regulation on the bacteria counts of *E. coli* or the coliform group, is not necessary at present.

(7) Other matters discussed

- The specifications of composition that requires an *E. coli*-negative test for frozen foods as an indicator for the lack of

fecal contamination has been functioning effectively as one of the check items for sanitation management in the manufacturing process. Another basis for not applying this specification is that the use of other harmful microorganisms as indicators for validating the presence of contamination by the hazardous substances is regarded to be potentially more effective compared to that of *E. coli*. In addition, for the avoidance of heath risks, it is important to ensure sanitation during the manufacturing processes and appropriate heating before consumption; moreover, preventing microbial contamination of the raw materials, including imported materials, is also important. In the future, risk management organizations should take into consideration the above points when reappraising the specifications of composition required for frozen foods.

- There are insufficient findings for enabling an assessment on the influence of long storage—one of the characteristics of frozen foods—on health risks.

4 Conclusion

(1) Based on the investigations made by the FSC, no health hazard associated with the consumption of frozen bread dough and its variations, including food poisoning, has been reported in the past either at home or abroad.

(2) According to the investigations made by the FSC, in case of room-temperature and cool bread dough and its variations, which represent approximately 90% of bread dough and its variations currently distributed in Japan, no health hazard following consumption of the relevant foods has been reported in the past either in Japan or abroad, despite the lack of special specifications of composition.

(3) Only if frozen bread dough and its variations are heated adequately, intestinal microorganisms—for which *E. coli* is considered to be an effective indicator—would presumably be killed.

In light of the results of this study, abolishing the *E. coli*-negative requirement for frozen bread dough and its variations, the main ingredient in which is wheat flour and which require heating before consumption, is unlikely to lead to an increase in health risks as long as the foods are sufficiently heated or baked before consumption.

(Reference data)

[1] Material 1 for the 7th Meeting of the Microorganisms Expert Committee: Food Safety Risk Assessment (Food Safety Notice No.0823004; dated August 23, 2005; issued by the Ministry of Health, Labor and Welfare) (September 6, 2005)

[2] Material 7 for the 7th Meeting of the Microorganisms Expert Committee: Food Safety Risk Assessment on Frozen Bread Dough and Its Variations with Wheat Flour as the Main Ingredient (September 6, 2005)

[3] Material 2 for the 7th Meeting of the Microorganisms Expert Committee: Risk Profile on Frozen Bread Dough (September 6, 2005)

[4] Material 2 for the 10th Meeting of the Microorganisms Expert Committee: Request for Submission of Data Associated with Food Safety Risk Assessment (Answer) (Notification No. 1019003 issued by the Standards and Evaluation Division, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor and Welfare; dated October 19, 2005) (November 15, 2005)

[5] Material 3 for the 7th Meeting of the Microorganisms Expert Committee: Fiscal 2005 Investigation on Standards for Frozen Foods—Roundup Report and Risk Profile (September 6, 2005)

[6] Material 4 for the 7th Meeting of the Microorganisms Expert Committee: Fiscal 2005 Investigation on Standards for Frozen Foods—Investigation on Actual Contamination Conditions (September 6, 2005)

[7] Material 5 for the 7th Meeting of the Microorganisms Expert Committee: Fiscal 2005 Test on Specifications and Standards for Food and Food Additives—Test on Frozen Bread Dough and Materials (September 6, 2005)

[8] Material 6 for the 7th Meeting of the Microorganisms Expert Committee: Fiscal 2005 Investigation Concerning Specifications for Frozen Foods—Collection of Data and Literature on Actual Contamination Status of Frozen Foods, Information Concerning Regulatory Status in Foreign Countries, etc. (September 6, 2005)

[9] Material 2 for the 11th Microorganisms Expert Committee: Manufacturing Process Flowchart for Bread Dough (material submitted to the Ministry of Health, Labor and Welfare) (December 27, 2005)

[10] K. S. Richter, E. Dorneanu, K. M. Eskridge, and C. S. Rao: Microbiological Quality of Flours. Cereal Foods World, 38, 367–369 (1993)

[11] Material 3 for the 13th Microorganisms Expert Committee: Food Safety Risk Assessment Research on Frozen Bread Dough (February 15, 2006)

[12] Material 1 for the 11th Microorganisms Expert Committee: Establishment of Microorganisms Specification for Frozen Bread Dough (December 27, 2005)